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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,723	12/17/2001	Kenya Shitara	249-243	6052

23117 7590 12/19/2005

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ARLINGTON, VA 22203

EXAMINER

GRUN, JAMES LESLIE

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 12/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,723

Applicant(s)

SHITARA ET AL.

Examiner

James L. Grun

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2005 and 07 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11,13-20 and 66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11,13-20 and 66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 December 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07 December 2005, requesting entry of the response filed 14 October 2005, is acknowledged and has been entered. Claims 11, 13-20, and 66 remain in the case.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant is now required to submit acceptable corrected drawings, suitable for printing, within the time period set in the Office action. See 37 CFR § 1.85(a). Submission of corrected drawings may no longer be held in abeyance pending the indication of allowable subject matter. Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.

The specification is objected to and claim 18 is rejected under 35 U.S.C. § 112, first paragraph, for the reasons of record that the claim contains subject matter which was not described in the specification, as originally filed, in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the invention as is now claimed. The specification, as originally filed, does not provide support for CDR-grafted antibodies comprising DNA as is now claimed.

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Applicant's arguments filed 14 October 2005 have been fully considered but they are not deemed to be persuasive. Notwithstanding applicant's argument to the contrary, the specification teaches plasmids containing nucleic acids encoding the antibodies, not antibodies comprising DNA as is still claimed in claim 18.

Claims 11, 13-20, and 66 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Claims not containing elements critical or essential to the practice of the invention, such as detecting steps for monocytes or macrophages and their differentiation, or antibody fragments having all of the CDRs of functional antibodies, are not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Merely contacting and determining reaction of antibody with a specimen is insufficient for detecting monocytes or macrophages and their differentiation. Other cells, such as endothelial cells, may be present in a specimen and detecting binding reaction of a specimen containing these cells to anti-VEGF Flt-1 receptor antibodies would not serve to detect monocytes or macrophages and their differentiation. One would not be assured of the ability to practice the methods in the absence of required functional fragments and steps.

Claims 11, 13-20, and 66 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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In claims 11, 13-20, and 66, the interrelationships of the components and steps of the method are not clear. In these claims it is not clear what is being determined because the first step positively recites differentiating a stem cell into a monocyte and/or a macrophage. Essential steps, such as active detecting steps for monocytes or macrophages and their differentiation, appear lacking in the instant claims. One cannot clearly detect monocytes or macrophages and their differentiation merely by determining antibody reactivity with a specimen, e.g. the specimen might contain endothelial cells.

Claims 15, 17, and 18 are vague and indefinite because it is not clear if the parenthetical recitations of accession numbers are intended as limitations or are merely exemplary of the hybridomas or plasmid-containing bacteria.

Applicant's arguments filed 14 October 2005 have been fully considered but they are not deemed to be persuasive. Notwithstanding applicant's argument to the contrary, all rejections under this statute have not been obviated by applicant's amendments for the reasons set forth above.

Claims 11, 13-20 and 66 are rejected under 35 U.S.C. § 103(a) as being unpatentable over either of Shitara et al. (EP '799) or Shitara et al. (US '160) in view of Kendall et al. (U.S. Pat No. 5,861,484), and either of Clauss et al. or Barleon et al. for reasons of record.

Claims 11, 13-20 and 66 are rejected under 35 U.S.C. § 103(a) as being unpatentable over either of Shitara et al. (EP '799) or Shitara et al. (US '160) in view of Kendall et al. (U.S. Pat No. 5,861,484), either of Clauss et al. or Barleon et al., and further in view of Rockwell et al. (U.S. Pat. No. 5,840,301) for reasons of record.

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In addition to the reasons of record, one of ordinary skill in the art would have had an extremely reasonable expectation of success in determining differentiated monocytes or macrophages in a sample because these cells are known to be mature cells having differentiated from stem/progenitor cells and, as set forth, in view of the known presence of the VEGF Flt-1 receptor on these cells (Clauss et al. or Barleon et al.).

Applicant's arguments filed 14 October 2005 have been fully considered but they are not deemed to be persuasive. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., detecting differentiation of hematopoietic cells negative for VEGF Flt-1 receptor surface expression into macrophages/monocytes having VEGF Flt-1 receptors) are not recited in the rejected claim(s) other than in the preamble. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Moreover, a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where, as herein, the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). The references as combined, for the reasons of record, teach the methods as claimed and determined antibody binding to a specimen containing mature monocytes or macrophages having differentiated from stem/progenitor cells.

No claim is allowed.

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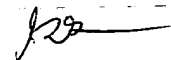
Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.

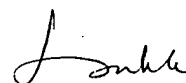
The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



James L. Grun, Ph.D.
December 9, 2005



LONG V. LE
SUPERVISORY PATENT EXAMINER
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12/09/05